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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,269	01/14/2004	George M. Halow	A-8051.CIP.RNFMP/bh	2686

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EXAMINER

CHOI, FRANK I

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/756,269

Applicant(s)

HALOW, GEORGE M.

Examiner

Frank I Choi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-41 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/17/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/43654 in view of Cleveland et al. (US Pat. 6,048,901), Wood et al. (US Pat. 5,498,425) and Vining (US Pat. 5,782,762).

WO 98/43654 teach a composition and method of purging the colon prior to colonoscopy, radiographic examination or bowel surgery containing sodium phosphate salts, including mono and dibasic salts) combined with polyethylene glycol, bisacodyl and cascara sagrada and that the composition can be administered in solid or liquid (aqueous) form (Pgs. 1, 7, 11). It is taught the combination of compounds are present in amounts effective to produce a purgative and/or laxative composition which evidences synergistic activity and that one of ordinary skill in the art may readily determine the amount and types of compounds/compositions to used in treating a particular patient (Pg. 11).

Cleveland et al. teach that polyethylene glycol is effective in reducing intestinal gases, cramping and/or anorectal irritation associated with constipation and which can be exacerbated by use of laxatives (Column 1, lines 14-30). It is taught that the composition is preferably substantially free of ancillary electrolytes as salts may exert a constipative effect (Column 45-

58). It is taught that the PEG polymer used is solid at room temperature and soluble with water and may be mixed with water or juice (Column 1, lines 58-68, Column 2, lines 1-20).

Wood et al. ('425) teach that cascara and bisacodyl are used for bowel clearance. It is taught that powders may be packaged in aluminum lined paper containers and that such packets are economical and easier to ship and store (Column 1, lines 6-12, Column 3, lines 4-7).

Vining teaches that in addition to using laxatives the patient should be put on a clear liquid diet to obtain a clean bowel for examination (Column 8, lines 1-20).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the combination sodium phosphate and PEG for use as a bowel cleanser. However, the prior art amply suggests the same as the prior art discloses the combination of PEG and sodium phosphate for use as a bowel cleanse. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the combination would be effective as a bowel cleanser for use in clearing bowel prior to examination procedures, the combination with PEG would reduce any intestinal gas or cramping which may be exacerbated by use of laxatives and that lack of ancillary salts would increase laxative effect due to reduced constipation.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

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Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Gary Kunz, can be reached at 571-272-0887. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

FIC

December 13, 2004



**S. MARK CLARDY
PATENT EXAMINER
GROUP 1200**
1616